Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class:	**Tramadol Therapy**
Date:	**March 15, 2006**
Prepared for:	**Missouri Medicaid**
Prepared by:	Heritage Information Systems, Inc.

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: Avoid unnecessary costs and negative health outcomes by ensuring appropriate use of tramadol.

Why was this Issue Selected: For the previous reporting period (April 2005 – March 2006), Missouri Medicaid paid $5.1 million for drug class. This represents 2.1% of the total drug budget.

Program-specific information:

Drug	Claims	Expense
• Ultram (tramadol)	*109,961*	*$1,613,433*
• Ultracet (tramadol/Apap)	*51,432*	*$3,506,098*
• Ultram ER (tramadol extended-release)	*5*	*$155*

Setting & Population: Patients 16 years of age and older

Type of Criteria:

☒ **Increased risk of ADE** ☐ **Non-Preferred Agent**

☐ **Appropriate Indications** ☐ **Other:**

Data Sources:

☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

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Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

Tramadol is an effective analgesic for the management of moderate to moderately severe pain. However, when used inappropriately, tramadol can be costly and can have a negative impact on patient health. The most commonly encountered adverse events include dizziness, sedation, headache, and gastrointestinal effects (nausea, vomiting, and constipation). Tramadol has also been associated with more serious adverse effects, such as seizures and abuse or dependence. While these adverse events can occur at recommended doses of tramadol, the incidence of seizures, as well as other adverse events is increased when tramadol is used at higher than recommended doses and when combined with certain other medications. The safety and efficacy of tramadol has not been established in patients less than 16 years of age.

The use of tramadol has also been associated with reports of abuse, dependence, and withdrawal. Abrupt discontinuation of tramadol has been noted to precipitate withdrawal symptoms in some patients. According to the manufacturer's package insert, tramadol use can also "reinitiate physical dependence in patients that have been previously dependent or chronically using other opioids."[1]

Setting & Population

- Drug/drug class for review: Tramadol products
  - Ultram – tramadol
  - Ultracet - tramadol/acetaminophen
  - Ultram ER – tramadol extended-release
- Age range: 16 years of age and older

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Approval Criteria

- Requests for tramadol therapy will be denied in the presence of denial criteria
- Ultram ER therapy requires trial and failure on regular release tramadol product

Denial Criteria

- 15 years of age or less
- Daily dose exceeds maximum recommended daily dose:
  - Patients ≤ 75 years of age – 400 mg
  - Patients > 75 years of age – 300 mg
- Presence of seizure history
- History of opioid abuse or dependence – therapy will be approval subject to Clinical Consultant review.

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐		

References

1. Connor EP, Murray L, et al., editors. Physicians' Desk Reference. New Jersey: Medical Economics Company; 2002 p2601.

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